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In the Supreme Court of the United States

AETNA HEALTH INC., FKA AETNA U.S. HEALTHCARE INC. AND AETNA U.S. HEALTHCARE OF NORTH TEXAS INC.,

Petitioner,

v.

JUAN DAVILA,

Respondent.

CIGNA HEALTHCARE OF TEXAS, INC., DBA CIGNA CORPORATION,

Petitioner,

v.

RUBY R. CALAD, et al.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

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BRIEF OF FAMILIES USA, et al. AS *AMICI CURIAE* IN SUPPORT OF THE RESPONDENTS

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INTEREST OF AMICI CURIAE[1]

Amici are consumer, disease and disability organizations that have worked for years to ensure that health care consumers receive affordable, high-quality health care coverage. Families USA is a national nonprofit, nonpartisan organization dedicated to achieving high-quality, affordable health care for all Americans. Through its Health Assistance Partnership project, Families USA works directly with patient advocates nationwide. These advocates are helping patients in all 50 states who have been denied critical treatments and services to negotiate with their health plans. The Arthritis Foundation is the nation's leading nonprofit organization dedicated to improving the lives of 70 million Americans through leadership in the prevention, control and cure of arthritis and related diseases. The Epilepsy Foundation is the sole national, charitable voluntary health organization dedicated to advancing the interests of the more than 2.5 million people with epilepsy and seizure disorders. The Spina Bifida Association of America's mission is to promote the prevention of spina bifida and to enhance the lives of all affected, it serves as the national representative of almost 60 chapters. The Brain Injury Association is the only national nonprofit agency working on behalf of the more than 1.5 million Americans who sustain a brain injury each year, the estimated more than 5.3 million Americans living with

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[1] Pursuant to Supreme Court Rule 37.6, amici state that no person or entity other than the amici curiae and their undersigned counsel made a monetary contribution to the preparation or submission of this brief. No attorney for any party authored this brief in whole or in part. Written consent to the filing of this brief has been obtained from the parties in accordance with Supreme Court Rule 37.3(a). Copies of the consent letters have been filed with the clerk.

permanent disabilities resulting from a brain injury, and their circles of support.

The American Association of People with Disabilities is the largest national cross-disability membership organization working to improve the political and economic empowerment of the 56 million children and adults with disabilities in the United States. The Arc of the United States, through its nearly 900 state and local chapters, is the largest national nonpartisan, nonprofit, voluntary organization in the United States devoted solely to the welfare of the more than seven million children and adults with mental retardation and related developmental disabilities and their families. The National Organization on Disability, founded in 1982, promotes the full and equal participation and contribution of America's 54 million men, women and children with disabilities in all aspects of life. ADAPT is a national nonprofit consumer organization whose members have severe disabilities and often rely on the health care system to remain as functional and independent as possible. Family Voices is a nonpartisan, nonprofit membership organization with 50,000 grassroots members and state coordinators in all 50 states and the District of Columbia, and is dedicated to addressing the needs and interests of children with special health care needs and their families. United Spinal Association (formerly Eastern Paralyzed Veterans Association) is a membership organization comprised of individuals who have incurred spinal cord injury or disease and who reside throughout the United States. Amputee Coalition of America is a national, nonprofit amputee consumer educational organization representing people who have experienced amputation or are born with limb differences. National Association of Protection and Advocacy Systems is the voluntary national membership organization of a nationwide network of congressionally mandated, legally based disability rights agencies. The Disability Rights Education and Defense

Fund, founded in 1979 by people with disabilities and parents of children with disabilities, is a national law and policy center dedicated to protecting and advancing the civil rights of people with disabilities. The National Health Law Program (NHeLP) is a national public interest law firm that seeks to improve health care for America's working and unemployed poor, minorities, the elderly and people with disabilities.

More than 120 million Americans receive their health care through managed care plans sponsored by private employers. Many of these Americans have chronic conditions or disabilities that necessitate frequent use of health care services. As patients in the health care system, they are likely to encounter denials of care due, in part, to the financial incentives inherent in many managed care arrangements. Many people with disabilities and chronic conditions are vulnerable consumers, ill-equipped to advocate for themselves in a timely manner. These patients tend to place great trust in their health plans to provide the services that are in their best medical interests in order to help them lead healthy and productive lives.

Amici believe that a patient's right to sue his or her health plan in state court for medically inappropriate denials of care is a powerful incentive for managed care plans to provide quality health care services to all patients, even those with extensive health care needs. A system that recognizes that a health plan's inappropriate medical decisions may result in serious consequences enhances accountability and quality health care for all Americans. Therefore, amici urge the Court to affirm the decisions of the Fifth Circuit in *Calad v. Cigna Healthcare of Texas, Inc.* and *Davila v. Aetna U.S. Healthcare, Inc.*

SUMMARY OF ARGUMENT

The shift many Americans have experienced in their health care from a fee-for-service arrangement to a managed care model has profoundly influenced the way people receive their health care and the kinds of decisions made each day by health insurers, including those insuring employer-sponsored plans. As this Court recognized in *Pegram v. Herdrich*, 530 U.S. 211 (2000), managed care entails direct influence and control over treatment by the parties responsible for paying for it. Indeed, the insurer's application of independent medical judgment to treatment recommendations by physicians is one of managed care's central features. Managed care entities routinely make decisions that determine what medical care a patient should receive while simultaneously determining what medical care the plan will cover, usually by judging whether a patient's requested treatment meets a plan requirement of "medical necessity."

The *Pegram* Court examined the dual nature of medical necessity determinations—"mixed treatment and eligibility decisions"—in the context of an action for breach of fiduciary duty under the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 *et seq.*, and determined that the partially medical nature of the decision made it non-fiduciary in nature. This distinction between plan administration on the one hand (regulated entirely by ERISA), and the exercise of professional judgment subject to standards of ordinary care on the other (regulated by state law even where an ERISA plan is involved), has long been recognized by courts as an important component of ERISA preemption analysis. ERISA simply does not contemplate the regulation of medical judgments, any more than it regulates the provision of other non-fiduciary professional services to an employee benefit plan.

ERISA preemption is not implicated where, as here, a patient has no cause of action under ERISA. The preemption question in this case turns on whether Respondents' state law claims state a cause of action that can be brought pursuant to ERISA Section 502, 29 U.S.C. § 1132. In particular, ERISA Section 502(a)(1)(B) provides a cause of action only where plan benefits are past due or will become due in the future. Where a participant has been injured by a mixed eligibility and treatment decision and, as a result, the denied benefits are no longer relevant or available to the participant, a state law cause of action for violation of the standard of care does not duplicate any ERISA claim.

The denials of Ms. Calad's and Mr. Davila's requests for particular treatments were mixed treatment and eligibility decisions like that analyzed in *Pegram*. The consequences of those decisions do not give rise to any cause of action under ERISA Section 502. The decision of the Fifth Circuit, finding no ERISA preemption and hence no federal jurisdiction over Respondents' claims, should be affirmed.

ARGUMENT

I. MANAGED CARE ENTITIES SEEK TO INDUCE A NEW, MORE COST-CONSCIOUS, AND SOMETIMES HIGHER-RISK STYLE OF MEDICAL PRACTICE.

As this Court recognized in *Pegram*, the previously distinct activities of paying for health care and providing health care services to individual patients are now "inextricably mixed." 530 U.S. at 229. Large health insurers and/or administrators, such as petitioners Aetna and Cigna in these cases, pay for (or administer payment for) the health care of millions of individuals and simultaneously seek, through financial incentives, practice guidelines, utilization review criteria, and other means, to shape and influence

the way doctors practice medicine and the care that patients actually receive. *See, e.g.*, David Blumenthal, *Effects of Market Reforms on Doctors and Their Patients*, 15 Health Affairs 170, 173-77 (Summer 1996). This is not a *sub rosa* enterprise. The explicit goal of "managed care" is to *manage care*, and the consequence is a new, more cost-conscious and sometimes higher-risk style of medical practice. *See, e.g.*, *Pegram*, 530 U.S. at 218-21 (citing literature, and noting that rationing "necessarily raises some risks while reducing others (ruptured appendixes are more likely; unnecessary appendectomies are less so)," *id.* at 221).

Indeed, when it is in their immediate legal interest to do so, managed care entities argue that they *are* engaged exclusively or primarily in health care delivery rather than in insurance or payment for care. *See, e.g.*, *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 366, 370 (2002); *McEvoy v. Group Health Cooperative of Eau Claire*, 213 Wis.2d 507, 570 N.W.2d 397 (Wis. 1997). The major private non-profit national accrediting entity for managed care, the National Commission on Quality Assurance (NCQA), measures such quality factors in a managed care entity as adolescent immunization status, antidepressant medication management, beta blocker treatment after a heart attack, screening for breast and cervical cancer, and comprehensive diabetes care. NCQA, Managed Care Organization Accreditation at 3, *available at* http://www.ncqa.org/Programs/Accreditation/MCO/images/1228_MCO%20Insert.pdf (last visited Jan. 16, 2004). In short, as this Court recognized in *Pegram*, far from being passive payors for care, managed care entities are actively involved in managing the quality of health care, and this role is manifested in the mixed eligibility and treatment decisions these entities make as to the care to be afforded to patients who are ERISA plan participants.

The facts in *Pegram* highlight the "intertwined" nature of the treatment and eligibility decisions made by managed care entities that contract with ERISA plans. Dr. Pegram was the treating physician and an employee/owner of the HMO. She decided that it was not necessary to send Ms. Herdrich to an out-of-network local hospital for a speedy ultrasound test. 530 U.S. at 215, 229. That decision was *simultaneously* a decision about the medically proper treatment for Ms. Herdrich as an individual, governed by the state law of medical malpractice, and about what the HMO would (and would not) pay for, governed by the plan contract. *See id.* at 229. Dr. Pegram's decision to subject Ms. Herdrich to the cheaper, delayed diagnostic test imposed additional risks, which materialized when Ms. Herdrich's appendix ruptured. *Id.* at 215.

Petitioners Aetna and Cigna's mixed eligibility and treatment decisions in these cases reflect the dual goals of managed care: to contain costs and influence the health care services actually delivered. Thus, Aetna's letter to Dr. Lopez refusing to pay for Vioxx and offering to pay for other pain medications begins as follows: "*As part of our commitment to provide access to quality care for our members*, Aetna U.S. Healthcare conducts a utilization review program with physicians, hospitals, and others who provide care, services and equipment to our members." App. to Pet'r's Cert. Pet. 80a (emphasis added). Cigna offers its patients "Case Management," which has as its stated goal

> to *ensure that patients receive appropriate care in the most effective setting possible* . . . . Should the need for Case Management arise, a Case Management professional will work closely with the patient, his or her family and the attending physician to determine appropriate treatment options which will best meet the patient's needs and keep costs manageable. The Case Manager *will help coordinate the treatment program and arrange for necessary resources.*

J.A. 204-05 (emphasis added). While nothing in the record establishes that such detailed Case Management was provided to Ms. Calad, the "Healthcare Management Guideline" that Cigna apparently used as the basis for discharging Ms. Calad from the hospital one day after her hysterectomy is titled "Case Management: Coordinate Care and Anticipate Needs." *Id.* at 295.

To be sure, Aetna, Cigna, and the managed care industry in general do not formally prohibit patients from paying out of their own funds for care that is denied on the basis of a lack of medical necessity. *See, e.g.*, Amicus Br. of American Association of Health Plans-Health Insurance Association of America, Inc. (AAHP-HIAA) 11 n.7. However, a great many patients cannot afford to purchase the services or pharmaceuticals for which managed care entities refuse to pay. As a practical matter, the decision by a managed care entity not to authorize payment for a certain treatment or course of action, often combined with the decision to pay for an alternative treatment or course of action, frequently dictates what care the patient will receive. *See, e.g.*, *Corcoran v. United HealthCare Inc.*, 965 F.2d 1321, 1324 (5th Cir. 1992) (involving utilization reviewer's refusal to authorize continued hospitalization recommended by treating physician for patient with high-risk pregnancy, which, combined with authorization of part-time at-home nursing care, allegedly contributed to death of fetus); *DiFelice v. Aetna U.S. Healthcare*, 346 F.3d 442, 463 (3d Cir. 2003) (Becker, J., concurring) (involving utilization reviewer's refusal to authorize a specially-designed tracheostomy tube, which, combined with authorization of standard tracheostomy tube, allegedly led to serious soft tissue and bone infection). Whether the patients in these cases accepted the treatments found medically necessary by the managed care entity because they could not afford the alternative or because they trusted the judgment of the managed care provider, the fact remains that the care authorized was the care provided.

As described above, in its coverage materials, accreditation standards, and communications with patients and providers, the managed care industry claims responsibility not only for lower costs but also for a high quality of patient care. As this Court and others have recognized, managed care seeks to influence, and does influence, the way providers practice and the services patients actually receive. *See, e.g.*, *Pegram*, 530 U.S. at 218-19; *Rush Prudential*, 536 U.S. at 366-67. When a managed care entity evaluates whether a requested treatment meets a plan requirement of "medical necessity" in a particular case, it determines what medical care the plan will cover while simultaneously determining what care a patient should receive. For these reasons, Aetna and Cigna cannot plausibly argue that they only made eligibility decisions and had no responsibility for the treatment (or lack of treatment) actually received by Ms. Calad and Mr. Davila.

II. INSTITUTIONS RESPONSIBLE FOR QUALITY OF CARE AND MANAGING MEDICAL RISK ARE TRADITIONALLY AND PROPERLY SUBJECT TO STATE LAW.

When hospitals became significant overseers of quality of care—a function reflected in the hospitals' own practices and accreditation standards—they were subjected to state licensure and to direct and vicarious tort liability. Thus, in *Darling v. Charleston Community Hospital*, 33 Ill. 2d 326, 211 N.E.2d 253 (1965), the court rejected a hospital's argument that it performed only administrative functions and that only physicians were responsible for health care services. The court found that argument inconsistent with hospitals' practices and licensing and accreditation standards. 33 Ill. 2d at 330-32. As managed care entities have assumed the same role through their influence on medical

practices and their accreditation by national organizations promoting their quality-enhancing function, they have been similarly subjected to state licensure, and (as recognized in *Pegram*) increasingly subjected to tort liability by state courts and legislatures for negligent exercises of medical judgment. *See, e.g., Jones v. Chi. HMO Ltd. of Ill.*, 191 Ill. 2d 278, 292, 730 N.E.2d 1119 (2000) (analogizing role of HMO to that of hospitals, and extending the *Darling* doctrine of institutional negligence to HMOs).

The literature indicates that the cost containment techniques of managed care directly affect the quality of care, in some cases by decreasing and, in others, by increasing risks to patients. For example, studies have found that managed care entities are better than fee-for-service providers at getting cardiac patients to take aspirin, but sometimes use lower-cost (and higher-mortality) hospitals for coronary artery bypass graft surgery. Joseph Gottfried & Frank A. Sloan, *The Quality of Managed Care: Evidence from the Medical Literature*, 65 Law & Contemp. Probs. 103, 107-08 (2002). Robert H. Miller and Howard S. Luft's 1997 literature survey (based on data primarily from the early 1990s) found evidence pointing both ways, with negative results focusing particularly on chronically ill and low-income enrollees. Robert H. Miller & Howard S. Luft, *Does Managed Care Lead to Better or Worse Quality of Care?*, 16 Health Affairs 7, 14 (Sept./Oct. 1997).[2]

Amicus AAHP-HIAA points to studies that document how patients enrolled in managed care entities have received

[2] *See also Zamora-Quezada v. HealthTexas Med. Group of San Antonio*, 34 F. Supp. 2d 433, 442 (W.D. Tex. 1998) (denying motion to dismiss by Texas HMOs sued under the Americans With Disabilities Act by patients and former doctors who alleged that patients with chronic conditions were repeatedly given substandard care, and that physicians were terminated because they advocated for their disabled patients).

the same or better quality of care than that received by patients in fee-for-service programs. *See* AAHP-HIAA Amicus Br. at 14-19. Indeed, AAHP-HIAA argues that "insurers and administrators, who compete for the business of [employers] and their employees, have no incentive to design systems that deny coverage for no good reason," particularly when "denial of some relatively inexpensive item or service would likely lead to a bad medical outcome that would then require additional, much more expensive care." *Id.* at 12-13.

This logic may appear plausible at first glance, but it overlooks several countervailing factors. First, coverage denials often do not involve "inexpensive items," but rather expensive items such as hospitalization or long-term physical therapy, the denial of which increases risk and causes harm. *See, e.g., McEvoy*, 213 Wis. 2d at 514-16 (involving allegations that HMO medical director refused to authorize continued hospitalization for anorexic patient, and instead authorized outpatient services, causing patient to lose 22 percent of her weight and require re-hospitalization); *Bedrick v. Travelers Ins. Co.*, 93 F.3d 149, 151 (4th Cir. 1996) (involving reviewing doctor's decision to deny continued intense physical therapy for infant with cerebral palsy). This is particularly true when a coverage denial will yield immediate savings, which the courts have recognized as creating a financial conflict of interest in coverage decisionmaking. *See, e.g., id.* at 152.

In addition, as noted by Judge Richard Posner, the "bad medical outcome" caused by HMO underservice might be death, which, by comparison with lengthy medical treatment, is the most profitable option for the HMO, given that no further benefits will be payable. *Blue Cross & Blue Shield United of Wis. v. Marshfield Clinic & Sec. Health Plan of Wis., Inc.*, 65 F.3d 1406, 1410 (7th Cir. 1995) ("[T]he HMO's incentive is to keep you healthy if it can but if you

get very sick, and are unlikely to recover to a healthy state involving few medical expenses, to let you die as quickly and cheaply as possible."). The availability of countervailing patient causes of action is particularly important when the financial incentives of at-risk, prepaid managed care push toward underservice of the seriously ill. For this reason, the vacuum that would be left by ERISA preemption would prevent the managed care system from functioning optimally to minimize patient risk while maximizing the affordability of employer-sponsored plans. Echoing Judge Posner's point, Dudley et al. state that

> [t]here are many theoretical reasons to believe that simple [non risk-adjusted] prepayment creates incentives to provide high-quality care to the healthiest members of a population, but a lower quality of care to enrollees with chronic disease. There is, however, at least one theoretical feature of HMOs that mitigates the incentives to skimp on care: an HMO becomes a deep pocket for lawsuits.

R. Adams Dudley *et al.*, *The Impact of Financial Incentives on Quality of Health Care*, 76 Millbank Q. 649, 662 (1998).

As the Court correctly noted in *Pegram*, the point is not a blanket condemnation of managed care. *Pegram*, 530 U.S. at 221. All health care financing and delivery arrangements increase some types of risks and diminish others. The question posed by the cases before this Court is whether our established state-level political and legal framework for dealing with the risks, costs, and benefits of health care delivery will be permitted to carry out its traditional role, a role for which ERISA was not intended and which it cannot play.

III. DECISIONS BASED ON MEDICAL JUDGMENTS AND OTHER EXERCISES OF STATE-REGULATED PROFESSIONAL JUDGMENT ARE NOT REGULATED BY ERISA.

A. Decisions Involving the Exercise of Medical Judgment Are Not Regulated by ERISA.

In *Pegram*, the Court utilized a three-part framework for analyzing the types of decisions made by HMOs regarding patients. "[P]ure 'eligibility decisions' turn on the plan's coverage of a particular condition or medical procedure for its treatment." *Pegram*, 530 U.S. at 228. In contrast, "treatment decisions" are "choices about how to go about diagnosing and treating a patient's condition: given a patient's constellation of symptoms, what is the appropriate medical response?" *Id.* However, as discussed above, the Court went on to note that these decisions are often inextricably mixed together, because "most coverage questions are not simple yes-or-no questions," but are instead "when-and-how" questions: that is, "whether one treatment option is so superior to another under the circumstances, and needed so promptly, that a decision to proceed with it would meet the medical necessity requirement that conditions the HMO's obligation to provide or pay for that particular procedure at that time in that case." *Id.* at 228-29. Dr. Pegram's decision regarding Ms. Herdrich's treatment (like Cigna's decision regarding Ms. Calad and Aetna's decision regarding Mr. Davila) was a mixed eligibility and treatment decision. *See id.* at 229-30. These mixed eligibility-treatment decisions, *Pegram* held, were non-fiduciary in nature, and therefore Ms. Herdrich could not state an ERISA claim for breach of fiduciary duty based on such a decision. *Id.* at 231-37.

For current purposes, *Pegram*'s important distinction is between "pure eligibility decisions" and "mixed eligibility

and treatment decisions." A pure eligibility decision is a relatively mechanical application of an eligibility rule that does *not* depend on medical judgment about an individual patient. In *Haynes v. Prudential Health Care*, 313 F.3d 330 (5th Cir. 2002), for example, the HMO refused to accept a referral to a specialist from a patient's doctor because, contrary to the patient's understanding, his doctor was not on the list of approved primary care physicians under the plan. *Id.* at 332. The result was that the HMO would not allow Mr. Haynes to receive care from the specialist, and he lost his leg. *Id.* at 332-33. As unfair as the result in *Haynes* may appear, from an ERISA preemption perspective the case was correctly decided: the decision to refuse treatment was based on a mechanical application of plan terms rather than a medical judgment and was therefore a pure coverage decision subject to preemption under ERISA's express preemption provision, ERISA § 514, 29 U.S.C. § 1144. The decision in *Haynes* was wholly consistent with the *Pegram* framework.

Pilot Life Insurance Co. v. Dedeaux, 481 U.S. 41, 43 (1987), in which the Court held preempted a plan participant's state-law claims for past-due disability benefits, also fits within that framework. Although medical facts may be relevant to decisions about whether individuals are entitled to monthly stipends by reason of "disability," such decisions differ fundamentally from decisions about a health care treatment's "medical necessity," because the former do not affect the medical treatment of the individual. Hence, Dedeaux's claim in *Pilot Life* that denial to him of disability insurance benefits had caused him harm was based solely on a denial of monetary benefits, not on a medical judgment as to treatment. The Pilot Life Insurance Co. did not wear two hats; its decisionmaking about disability insurance was only about eligibility for money. In contrast, as *Pegram* explained, mixed eligibility and treatment decisions do not

fit well into Congress's focus in ERISA on decisions about monetary assets. *Pegram*, 530 U.S. at 230-32.

Nor is the holding in *Pegram* limited to the situation where a treating physician is making the medical necessity determination. *Id.* at 228 (stating that the "inextricable" mixture of treatment and eligibility "is so not merely because . . . treatment and eligibility decisions are made by the same person."). The important fact for the analysis is not the identity of the particular decisionmaker within the managed care entity, but the partially medical character of the decision made. *See Land v. Cigna Healthcare of Fla.*, 339 F.3d 1286, 1288-89 (11th Cir. 2003) (considering decision made by "approval nurse"); *Cicio v. Does*, 321 F.3d 83, 88 (2d Cir. 2003) (considering decision by plan's medical director).

B. Decisions Involving Other Exercises of Professional Judgment Are Not Regulated by ERISA.

The distinction between plan administration and the exercise of professional judgment by non-fiduciaries has been understood by courts for years as an important component of ERISA preemption analysis. The federal courts have consistently rejected the notion that ERISA federalizes the regulation of professional services provided by non-fiduciaries in connection with ERISA plans. *See, e.g., Airparts Co., Inc. v. Custom Benefit Servs. of Austin*, 28 F.3d 1062, 1065 (10th Cir. 1994) (finding no ERISA preemption of state law professional negligence and other claims against outside consulting firm hired to advise trustees concerning actuarial calculations and other plan matters); *Gerosa v. Savasta & Co., Inc.*, 329 F.3d 317, 324 (2d Cir. 2003) (noting that "courts routinely find that garden-variety state law malpractice or negligence claims against non-fiduciary plan advisors, such as accountants,

attorneys, and consultants, are not preempted" and collecting cases); *Custer v. Sweeney*, 89 F.3d 1156, 1166-67 (4th Cir. 1996) (joining "unanimous body of federal law" holding that state law malpractice claims involving non-fiduciary professional services to ERISA plans are not preempted); *see also Painters of Phila. Dist. Council No. 21 Welfare Fund v. Price Waterhouse*, 879 F.2d 1146, 1152-53 & n.7 (3d Cir. 1989) (noting that professional malpractice actions are analogous to the state law claims held not preempted in *Mackey v. Lanier Collection Agency & Serv.*, 486 U.S. 825 (1988)); *Mertens v. Kaiser Steel Ret. Plan,* 829 F. Supp. 1158, 1161-62 (N.D. Cal. 1992) (holding that where plan participants alleged that negligent provision of actuarial services caused underfunding of their pension plan, depriving them of benefits, their claims were *not* preempted by ERISA). Thus, medical judgments are not the only types of actions affecting plan participants and beneficiaries that are unregulated by ERISA and that have been held not to be preempted by ERISA.

C. The *Pegram* Framework Should Guide Preemption Analysis in Cases Involving Medical Benefits.

The analytical framework of *Pegram*—analyzing the nature of a claim based on the nature of the challenged decision—carries the same logical force in a preemption context as it did in analyzing the availability of an ERISA fiduciary breach claim in *Pegram*. Indeed, this Court has acknowledged *Pegram's* applicability in a preemption context. Two years before *Pegram*, the Pennsylvania Supreme Court considered whether ERISA preempted a state law negligence claim against an HMO. The HMO, through a reviewing doctor, had refused to authorize a patient's transfer to an out-of-network hospital for immediate emergency care. Instead, it required the patient to wait

for treatment at an in-network hospital, allegedly resulting in the aggravation of his injury. *Pappas v. Asbel* (*Pappas I*), 555 Pa. 342, 344-45, 724 A.2d 889 (Pa. 1998). After handing down its decision in *Pegram*, this Court granted the defendants' petition for certiorari in *Pappas*, vacated the judgment, and remanded "for further consideration in light of *Pegram*." *U.S. Healthcare Systems of Pa., Inc. v. Pa. Hosp. Ins. Co.*, 530 U.S. 1241 (2000). The Pennsylvania Supreme Court then applied the *Pegram* framework to the issue of whether ERISA Section 514 preempted the state law negligence claim. It determined that the HMO's decision had involved a judgment about what constituted appropriate, safe medical care, and that, following *Pegram*, the decision's validity was properly tested through state malpractice law. *Pappas v. Asbel* (*Pappas II*), 564 Pa. 407, 419-20, 768 A.2d 1089, 1096 (Pa. 2001), *cert. denied,* 536 U.S. 938 (2002).

That *Pegram* applies to preemption cases, as this Court instructed the Pennsylvania Supreme Court, has also been understood by the lower federal courts. The Eleventh Circuit recently held that a patient could pursue a state law medical malpractice claim against his HMO based on a decision by a CIGNA "approval nurse" that the patient should receive outpatient care for an infected cat bite on his hand, rather than the inpatient care his treating doctors had recommended, allegedly leading to the amputation of his finger. *Land*, 339 F.3d at 1288-89. Applying *Pegram*, the Eleventh Circuit found that the decision was outside the scope of ERISA regulation because it was based in part on medical judgment. *Id.* at 1293-94.

The Eleventh Circuit could not have found Mr. Land's claim preempted without arrogating to the federal courts the field of state-law medical malpractice, *id.* at 1293, a drastic change not lightly made unless it was the "clear and manifest purpose of Congress." *New York State Conference*

of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995). Indeed, this Court has cautioned that preemption of state regulation in the field of health care is not to be lightly inferred, requiring a "clear manifestation of congressional purpose" to preempt such regulation. *Pegram*, 530 U.S. at 237 (citing *Travelers*). States defined standards of medical decisionmaking long before the existence of ERISA-covered plans. Because these standards of care are independent of ERISA, ERISA does not preempt actions based on application of these standards to a medical judgment based on a patient's particular "constellation of symptoms." *See Pegram*, 530 U.S. at 228; *Cicio*, 321 F.3d at 103-04.

The Second Circuit also considered *Pegram* in a preemption context in *Cicio v. Does*, 321 F.3d 83, 102 (2d Cir. 2003). In *Cicio*, the court of appeals found that a determination by a plan administrator's medical director regarding the experimental nature of a course of treatment may have rested on analysis of what was appropriate treatment for the particular patient. *Id.* at 91. Such a decision would be a mixed eligibility and treatment decision that could be challenged under state law after *Pegram*. *Id.* at 102 (citing *Pegram*, 530 U.S. at 229-30). The court of appeals noted its "skepticism of a line of reasoning that would draw from a comprehensive statute designed to promote the interests of employees and their beneficiaries in employee benefit plans the elimination of protective standards of professional conduct." *Id.* at 103-04 (internal quotation marks and citation omitted).[3]

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[3] The distinction between medical judgments and plan administration drawn in *Pegram* is nothing new: the same concept has long guided courts in analyzing whether state law claims were properly removed as completely preempted by ERISA. *See, e.g.*, (continued...)

IV. STATE LAW CLAIMS BASED ON THE CONSEQUENCES OF MANAGED CARE MEDICAL JUDGMENTS ABOUT THE TREATMENT OF INDIVIDUAL PATIENTS ARE NOT PREEMPTED BECAUSE THEY DO NOT DUPLICATE CLAIMS TO RECOVER PLAN BENEFITS OR ENFORCE OR CLARIFY PLAN RIGHTS UNDER ERISA § 502(a)(1)(B).

A. ERISA Does Not Preempt State Law Here Because It Does Not Duplicate the Elements of a Cause of Action Under ERISA Section 502(a)(1)(B).

In contrast to the claims here, ERISA preempts only those state laws that "duplicate[ ] the elements of a claim available under ERISA." *Rush Prudential,* 53 U.S. at 379 (discussing *Ingersoll-Rand Co. v. McClendon,* 498 U.S. 133 (1990)). In *Ingersoll-Rand*, a Texas law that provided a cause of action for wrongful discharge where the employer's

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(...continued)
Dukes v. U.S. Healthcare, Inc., 57 F.3d 350, 356-57 (3d Cir. 1995) (drawing distinction between claims attacking the "quality" of benefits provided versus claims attacking the "quantity" (e.g. erroneous withholding of benefits)); *Pacificare of Okla., Inc. v. Burrage*, 59 F.3d 151 (10th Cir. 1995) (allowing patient to proceed with medical malpractice action against HMO based on vicarious liability for doctor's malpractice, while finding related claim based on fraudulent plan administration completely preempted by ERISA); *Lupo v. Human Affairs Int'l, Inc.*, 28 F.3d 269 (2d Cir. 1994) (rejecting argument that claim was completely preempted because patient received psychotherapy services pursuant to ERISA-governed plan, where suit was based not on claim for benefits but on negligent treatment and misuse of information). *Cf. Lazorko v. Pa. Hosp.*, 237 F.3d 242, 249-50 (3d Cir. 2000) (holding that quality-quantity distinction was consistent with *Pegram*).

action was alleged to be motivated by a desire to avoid paying benefits clearly duplicated the cause of action provided by ERISA Section 510, which makes it unlawful for any person to take an adverse employment action against a plan participant "for the purpose of interfering with the attainment of any right to which such participant may become entitled under the plan," and was therefore preempted. 29 U.S.C. § 1140; *see Rush Prudential*, 536 U.S. at 379 (discussing *Ingersoll-Rand*).[4]

Likewise, Section 502's preemptive force was originally brought to bear on state law claims by a participant who *could have brought at the time of filing of the lawsuit* an ERISA cause of action for past-due disability benefits, but sought to bring state law claims for damages instead. *Pilot Life,* 481 U.S. at 43-44. Those claims did not fall within the insurance savings clause of ERISA Section 514 and therefore were expressly preempted. *Id.* at 57.

B. The Section 502(a)(1)(B) Cause of Action Is Limited to Circumstances Where Benefits Are Past Due or May Become Payable in the Future.

As the Fifth Circuit correctly held, neither Section 502(a)(1)(B) nor any other subsection of ERISA Section 502 provides a cause of action arising out of injuries alleged to have been caused by the failure of an HMO to exercise ordinary care when making medical judgments. *See Roark v. Humana, Inc.*, 307 F.3d 298, 309 (5th Cir. 2002). Causes of action under ERISA Section 502(a)(1)(B) are limited to circumstances in which a participant or beneficiary seeks

[4] Section 510 is enforced by means of an action under Section 502(a)(3). *Tolle v. Carroll Touch,* 977 F.2d 1129, 1133 (7th Cir. 1992).

"to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." 29 U.S.C. § 1132(a)(1)(B); *see Fallick v. Nationwide Mut. Ins. Co.*, 162 F.3d 410, 418 (6th Cir. 1998) (noting that ERISA Section 502(a)(1)(B) "provides a contract-based cause of action to participants and beneficiaries to recover benefits, enforce rights, or clarify rights to future benefits under the terms of an employee benefit plan"). Thus, Section 502(a)(1)(B) encompasses only those circumstances where benefits are past due or may become payable in the future. *See, e.g., Welsh v. Burlington Northern, Inc. Employee Benefits Plan*, 54 F.3d 1331, 1340 (8th Cir. 1995) (holding Section 502(a)(1)(B) empowers courts to calculate amount of benefits due); *Halpin v. W.W. Grainger, Inc.*, 962 F.2d 685, 697 (7th Cir. 1992) (holding Section 502(a)(1)(B) supports an order for reinstatement of terminated disability benefits).

C. Neither Mr. Davila's Nor Ms. Calad's Claim Duplicates an ERISA Section 502(a)(1)(B) Claim.

Mr. Davila's and Ms. Calad's circumstances do not give rise to a cause of action under Section 502(a)(1)(B) to recover benefits due or to enforce rights under their plans because there are no benefits owing or potentially owing to them. The benefits they previously sought are no longer medically necessary, so Respondents are no longer entitled to them under the terms of their plans: Vioxx is no longer a medically appropriate treatment for Mr. Davila, and additional hospitalization following surgery is no longer medically necessary for Ms. Calad. For the same reasons, neither Respondent will have a Section 502(a)(1)(B) cause of action to clarify his or her right to these same benefits in the future. Mr. Davila can no longer take Vioxx and Ms. Calad obviously cannot undergo another hysterectomy.

Accordingly, Respondents' causes of action under the THCLA do not arise out of any circumstances within the scope of ERISA Section 502(a)(1)(B).

Ms. Calad's and Mr. Davila's cases are distinguishable from *Pilot Life* in two respects. First, as discussed above, unlike Dedeaux, neither Ms. Calad nor Mr. Davila has a current cause of action under ERISA to recover benefits due under a plan. The services previously at issue are no longer appropriate or even feasible for them. Second, their current causes of action are not based on failure to deliver the contractual plan benefits, but on the consequences of the medical judgments applied to their care. The fact that Respondents had Section 502(a)(1)(B) causes of action to enforce plan terms at some point in the past does not affect the state law causes of action currently available to them. It is true that, had Ms. Calad been able to obtain from her hospital bed counsel willing and able to seek an immediate temporary restraining order compelling Cigna to keep her in the hospital, that cause of action would have arisen under Section 502(a)(1)(B), and Ms. Calad would not have suffered the injuries that she now seeks to redress. It is also true that, had Ms. Calad had the means to pay for her additional hospital stay out of pocket, she might now have a contractual reimbursement claim under Section 502(a)(1)(B), and again would not have suffered medical injuries. Anyone would rather suffer monetary loss than physical injury, but the plaintiffs in these cases were unable to avoid the physical injuries they suffered.

Thus, as a practical matter, neither a restraining order nor out-of-pocket payment for medical treatment is available to participants in many circumstances. For this reason, it is not correct to say that because these participants had a theoretical option to pursue ERISA causes of action, however fleetingly, before they were ever injured, their state law causes of action are alternative to those now-foreclosed ERISA claims. Neither *Pilot Life* nor *Ingersoll-*

Rand dictates a contrary conclusion; rather, they merely stand for the proposition that where both ERISA and state law provide causes of action arising out of the same injury, then the preemptive force of ERISA's enforcement scheme displaces state law. Accordingly, the Fifth Circuit was correct in holding that federal jurisdiction over Respondents' claims was lacking.

CONCLUSION

The decision of the Fifth Circuit should be affirmed.

Respectfully submitted,

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